APR 3 2006

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter: K052118

Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Contact: Tammy B. Carrea, Director Regulatory Affairs
Phone: (919) 465-2236 ext. 225
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Prepared: August 3, 2005

Common or Usual Name:	Patient Radiation Dosimeter
Proprietary Name:	DVS, Dose Verification System
Classification Name:	Accelerator, Linear, Medical
Manufactured By:	Sicel Technologies, Inc. 3800 Gateway Centre Blvd. Suite 308 Morrisville, NC 27560 Phone: (919) 465-2236 Fax: (919) 465-0153

Predicate Device(s): K052118

Thomson Nielsen
K932598, K013279, K010472, K032725, and K041557
TN-RD-50, MOSFET Autosense Wireless Dosimetry System, mobileMOSFET Dosimetry System

Sicel Technologies, Inc.
K040687
OneDose Patient Dosimetry System

Symbiosis
K925416
Bone Biopsy Needle

Device Description:

The DVS, Dose Verification System consists of four sub-systems: the DVS Implantable Dosimeter for measuring radiation dose *in vivo*, the DVS Insertion Tool for implanting the dosimeter during percutaneous procedures, the DVS Reader System (Wand and Base Station) for powering the dosimeter and providing a user interface when taking dose measurements, and the DVS Data System (Plan and Review Software and Dosimetery Database) for storing and reporting patient data and for storing dosimeter information. The dosimeters use a MOSFET, Metal Oxide Semiconductor Field Effect Transistor as a sensing mechanism. The dosimeter is factory calibrated and powered by the Reader Wand utilizing electromagnetic energy. The dosimeter contains a transmitter, to transmit threshold voltage readings to the reader. It is radioopaque and thus registers on computed tomography scans as a point of interest whereby a point dose may be determined. Patients are implanted prior to radiotherapy. Information on the patient's therapy, dose planning, point dose at the dosimeter, dosimeter serial number and calibration files are entered into the Plan and Review software and stored in the Dosimetry Database. At each therapy fraction the dosimeter is read pre- and post-therapy using the Reader Wand and Base Station. This translates into a daily fractional dose. The patient's daily and cumulative dose may be reviewed via the Plan and Review software. Because the Plan and Review software and Dosimetry Database are designed to be stored on a server, up to 25 users may be logged into the system at any one time. Reports on the patient's daily and cumulative dose history may be printed using the Plan and Review software.

Indication for Use: K052118

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

The DVS system is specifically indicated for breast cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

Comparison with Predicate Device:

The intended use of the SICEL DVS is identical to predicates such as the Thomson Nielsen Dose Verification System (K932598, K013279, K010472, K032725, and K041557) to verify that the radiation dose delivered corresponds to the dose plan.

The indications for use of the SICEL DVS also are substantially the same as the indications for use of the Thomson Nielsen device. Although the SICEL DVS is indicated for use to measure dose at the tumor's periphery, tumor bed, or in the surrounding tissue, while the Thomson Nielsen device is indicated for use to measure dose delivered "to the patient," the Thomson Nielsen device may be used for intracavity placement and, in conjunction with associated software, is able to calculate the dose delivered within the patient's body as a midline dose.

The technological features of the SICEL DVS are substantially the same as the predicates, including the use of MOSFET technology, as in the Thomson Nielsen device and the OneDose. The calibration, dose range, energy sources measured, and dose management software also are very similar to the Thomson Nielsen device.

There are three technological differences: the DVS is implantable, and because it is implantable materials and duration of use are different, and the DVS is telemetric and not tethered. Several other oncology devices currently marketed including brachytherapy seeds and radiographic marks are similar in size, position of implantation *in vivo*, use similar implantation techniques and tools, and are designed for permanent implantation. In addition other devices such as the Given Imaging Capsule, Cortemp Ingestible Capsule, and the Verichip Microtransponder, transmit data telemetrically to a reader system. The Given Imaging Capsule, the Jones Tube, and the Verichip Microtransponder also utilize similar materials contained within the DVS implantable dosimeter and are a similar size. Performance studies, pre-clinical studies, and clinical studies contained within the 510(k) are described in sufficient detail to demonstrate that the DVS is safe and effective and that the technological differences described here do not present any new issues of safety and effectiveness compared to

other currently marketed devices. K052118

The DVS, Dose Verification System is calibrated at the factory using the same method as the Thomson Nielsen for evaluating radiation units/volts except that the DVS, Dose Verification System is calibrated under controlled conditions at the factory and the Thomson Nielsen device must be calibrated by the user. Also the OneDose Dosimeter is likewise factory calibrated and the factory calibration is verified by an external ADCL lab in the same manner as the OneDose. The factory calibration procedure is described in sufficient detail within the 510(k) to demonstrate the methods used to assure calibration and the data contained with the performance data section demonstrates that calibrated devices perform within the stated performance specifications of the labeling.

The DVS, Dose Verification System is a sterile, single use dosimeter.

Thus, the DVS, Dose Verification System is substantially equivalent to the Thomson Nielsen Patient Dose Verification System (K932598, K013279, K010472, K032725, and K041557), OneDose Patient Dosimetry System (K040687), and the Symbiosis Bone Biopsy Needle (K925416).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

Ms. Tammy B. Carrea
Director, Regulatory Affairs
Sicel Technologies, Inc.
3800 Gateway Centre Boulevard
Suite 308
MORRISVILLE NC 27560

Re: K052118
Trade Name: DVS, Dose Verification System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN and NZT
Dated: December 30, 2005
Received: January 3, 2006

Dear Ms. Carrea:

This letter corrects our substantially equivalent letter of April 3, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

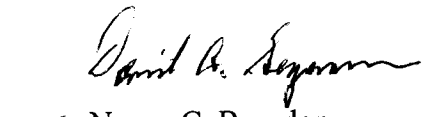
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K052118

Device Name: DVS, Dose Verification System

Indications for Use:

Intended Use

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

Indications for Use

The DVS system is specifically indicated for breast cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

David A. Segroves
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052118

(Optional Format 1-2-96)